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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/199,129	11/24/1998	JOSEPH R. BYRUM	38-2115075B	3322

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EXAMINER	
EPPS FORD, JANET L	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/199,129	BYRUM ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. On February 16, 2005 the Board of Patent Appeals and Interferences entered an order dismissing the Appeal filed by Applicants on July 2, 2002 in response to the Request for Continued Examination filed by Applicants on January 26, 2005.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 1-26-05 has been entered.

Claim Rejections - 35 USC § 101

3. Claims 4-12 stand rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and/or substantial utility or a well-established utility.

4. Applicant's arguments filed 1-26-05 have been fully considered but they are not persuasive. Applicants traversed on the grounds that the claimed plants and methods cannot be based solely on the utility of the nucleic acid molecules, but must be based on the claimed subject matter as a whole. According to Applicants the Examiner's apparent assertion that the patentability of the claims is based on the utility of SEQ ID NO: 1 alone is improper, because the claimed plants and methods exhibit the requisite utility apart from the utilities of the nucleic acid sequence. Moreover, according to Applicants "[t]he skilled artisan would recognize that such transformed plants can be more easily followed through a breeding program by the detection of

the nucleic acid molecule. These utilities are immediately apparent for the claimed plants and methods without the need for further research. Moreover, the claimed methods find use in determining the level or pattern of a protein in a plant tissue or cell. Specification at page 44, line 20 through page 48, line 21. For example, such methods can be used to assay gene expression in plant cells treated with an herbicide to detect target genes for producing herbicide tolerant plants. As such, the claimed methods also have a legally sufficient utility." In view of the above, Applicants concluded that the claimed plants and methods are supported by credible, specific, and substantial utilities disclosed in the specification. Furthermore, Applicants asserted that "[t]he Examiner has failed to raise any credible evidence challenging the presently asserted utilities. An invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101 Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under 35 U.S.C. § 101 is improper."

5. Contrary to Applicant's assertions, the rejection is considered proper based upon "The Revised Interim Utility Examination Guidelines" [published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136, Feb. 29, 2000, with a correction at 65 FR 3425, Jan. 21, 2000, and effective as of January 5, 2001.] According to the guidelines in order for an invention to have a well-established utility, the asserted utility must be specific, substantial, and credible. If the utility fails to be specific, substantial or credible, a rejection under 35 USC § 101 is considered proper (see page 9 of the guidelines). MPEP § 2107.01[R-1], states that a "specific utility" is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. This section also states that "basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved," or methods "of

assaying for or identifying a material that itself has no specific and/or substantial utility," does not define inventions that have "substantial utilities."

6. In the instant case, the specification does not disclose or provide any evidence that points to a specific or substantial biologically significant activity for nucleic acid comprising SEQ ID NO: 1, a plant comprising said nucleic acid, or a method of identifying an unknown protein, such that another non-asserted utility would be well established. Additionally, there is no art of record that discloses or provides any evidence that points to an activity for SEQ ID NO: 1 or its corresponding full length cDNA or the proteins that might be obtained using the full length cDNA to be obtained, such that another non-asserted utility would be well established.

In regards to Applicant's assertion that the claimed transformed plants can be more easily followed through a breeding program by the detection of the nucleic acid molecule. It is noted that the use that Applicants refers to is directed to basic research that involves studying the properties of the claimed transformed plant, and is therefore not considered a "substantial utility." Moreover, the asserted utility is not considered specific, since the recited use can be generally applied to any plant transformed with any cDNA molecule or fragment thereof.

In response to Applicant's assertion that the claimed methods can be used to assay gene expression in plant cells treated with an herbicide to detect target genes for producing herbicide tolerant plants, the recited use can be generally applied to any cDNA or fragment thereof. Furthermore, the method involves assaying for nucleic acid having (or comprising) SEQ ID NO: 1, however as stated above methods assaying for material that itself has no specific an/or substantial utility, does not define a substantial invention. Since no specific biological function has been ascribed to the nucleic acid comprising SEQ ID NO: 1 as recited in the claims, or its

corresponding putative protein, asserting that the nucleic acid can be used to follow a transformed plant through a breeding program, or used to monitor gene expression in plant cells is non-specific. These general uses are non-specific in the absence of any biological function disclosed for the nucleic acids comprising SEQ ID NO: 1, plants transformed with this sequence, or methods of assaying for this nucleic acid. SEQ ID NO; 1 has only been disclosed as an EST, without any known biological function and without any open reading frame. The specification as filed does not disclose or provide any evidence that points to an activity or phenotype associated with plants transformed with nucleic acids consisting of or comprising SEQ ID NO: 1, or the possible protein that can be obtained using the nucleic acid such that another non-asserted utility would be well established. Therefore, contrary to Applicant's assertions, Applicants have not identified any practical benefit of either the claimed plant or methods since neither the specification as filed, nor the prior art teaches or provides any evidence that defines any beneficial biological activity for the nucleic acid that is transformed into the claimed plant, or assayed for in the claimed methods.

In response to Applicant's arguments that the claimed plants and methods are supported by credible, specific, and substantial utilities disclosed in the specification, and that an invention need only provide one identifiable benefit to satisfy 35 USC § 101. The examiner agrees that the invention need only provide one identifiable benefit to satisfy 35 USC § 101, however it is also required that the benefit or utility be credible, substantial, *and* specific.

Since Applicants must perform further experimentation to identify the full length cDNA, and furthermore to identify the claimed transformed plant comprising the structural nucleic acid molecule "comprising" SEQ ID NO: 1 or its complement, at the time of filing of the instant

invention the person of ordinary skill in the art would not accept that the recited or disclosed plant was currently available for any beneficial or practical use. Moreover, since the biological activity of the full length cDNA potentially identified by using SEQ ID NO: 1 was not known, further experimentation is required to identify the biological activity associated with the full length cDNA, and the protein it encodes, in order for the skilled artisan to recognize how to use the claimed transformed plants. Additionally, in regards to the claimed methods for determining a level or pattern of a protein in a plant comprising the use of a marker nucleic acid which specifically hybridizes to a nucleic acid molecule having (comprising) SEQ ID NO: 1 or complement, it is apparent that further experimentation would be required first to identify the full length cDNA comprising SEQ ID NO: 1, isolate the protein encoded by the full length cDNA, and furthermore identify the biological activity of the encoded protein. Once the biological activity of the protein is identified, the skilled artisan would be able to identify a real-world context of use for the claimed methods. Without identifying the biological activity of the encoded protein, the skilled artisan would not be able to recognize the real-world context of use of the claimed method, therefore it is apparent that at the time of the instant invention the person of ordinary skill in the art would not accept that the recited or disclosed plant was currently available for a particular use. Basic research such as studying the properties of the claimed product itself or the mechanism in which the material is involved is not a substantial utility. There is insufficient support in the specification to indicate that the present invention as claimed meets the criteria of a specific and substantial and credible utility or, in the alternative, a well-established utility. Applicant has not identified a specific and/or substantial utility, thus the claimed invention is not presumed to possess it.

Claim Rejections - 35 USC § 112

7. The rejection of claims 4-12 under 35 U.S.C. 1 12, first paragraph, is maintained because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, for the reasons set forth above. Applicant's arguments have been fully considered, but as set forth above, the utility of the claimed nucleic acids has not been established and thus the ordinary skilled artisan would not know how to use a plant comprising a nucleic acid of unknown utility or how to practice a method comprising assaying for a nucleic acid of unknown utility, the rejection is therefore maintained.

8. Claims 4-12 stand finally rejected under 35 U.S.C. 1 12, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, for the reasons of record set forth in the Examiner's Answer mailed 10/23/2002.

Applicant's arguments filed 1-26-2005 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that description as filed is presumed to be adequate, unless and until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. According to Applicants the examiner presents no findings of fact to rebut the presumption that the written description in the specification is adequate, the only fact alleged by the Examiner in support of the written description rejection is that the claims encompass a sequence that is less than a full-length CDNA, and thus the sequences do not meet the written description requirement. Applicants assert that the following is described in the specification: transformation of plants with vectors

having the claimed nucleic acid molecules see, e.g., specification at page 66, line 12 through page 75, line 10) as well as methods for determining gene expression see, e.g., specification at page 15, lines 3-16 and page 47, line 8 through page 50, line 15). In light of the detailed disclosure of the present application, Applicants argued that one skilled in the art, after reading the present specification, would clearly know if a transformed plant or method contained the recited nucleotide sequences.

Contrary to Applicant's assertions, the breadth of the instant claims are directed to plants transformed with nucleic acids encompassing full length gene sequences (i.e. gene sequences yet to be discovered) and cDNAs comprising SEQ ID NO: 1, sequences that hybridize to SEQ ID NO: 1, and methods which utilize said sequences. However, none of these sequences meet the written description provision of 35 USC 1 12, first paragraph. For example, a cDNA comprising a partial sequence, as claimed, encompasses a wide variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its coding region, however, the specification does not disclose an open reading frame for SEQ ID NO: 1 and, therefore, would not be representative of the breadth of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule would be disclosed. In the instant case, the specification discloses only a single common structural feature shared by the claimed genus, i.e. SEQ ID NO: 1, and this disclosed structural feature does not constitute a substantial portion of the claimed genus, since there is no coding region disclosed as being associated with this sequence. The specification provides insufficient written description to support the genus encompassed by the claims.

Contrary to Applicant's assertions, the invention was not sufficiently reduced to practice such that the skilled artisan would recognized that Applicants were in possession of the full scope of the claimed invention.

Applicants are directed to the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention."

As stated above "[A]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." In the instant case, since Applicants must perform further experimentation to identify the full scope of nucleic acid sequences comprising SEQ ID NO: 1 encompassed by the instant claims, and the full scope of transformed plants encompassed by the claims, and the method of use comprising the use of the full scope of nucleic acid acids comprising SEQ ID NO: 1, Applicants have not

provided sufficient evidence that Applicants were in possession of the full scope of the claimed invention as of the filing date of the instant application. Moreover, since further experimentation is required to describe the full scope of the claimed invention, Applicant's invention was not "ready for patenting" or sufficiently reduced to practice at the time of filing of the instant invention. Therefore, contrary to Applicant's assertions, Applicants were not in possession of the full scope of the claimed invention at the time of filing.

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Epps-Ford, Ph.D.
Patent Examiner
Art Unit 1635

JLE